APR 2 3 2003

K024342

510(k) Summary of "DAITO CO., LTD."(FDA 501(k) Number: K024342)

(a)

(1) Submitter's name: DAITO CO., LTD.
address: 6-15-15 SANGA, DAITO-SHI, OSAKA 574-0077, JAPAN
telephone no.: 81-72-875-5171
contact person: Mr. Hiroshi Tanaka
The date the summary was prepared: March 27/2003

(2) The name of the device: Radiographic Film Processor
Classification name: Automatic Radiographic Film Processor

(3) Identification of legally marketed device: AFP Mini Med/90, AFP Mini Med

(4) Description of the device that is the subject of the premarket notification: submission:
*Designed solely for processing of radiographed films, by roller transport system and by use of developer/fixer solutions(that are to be locally obtained).
Significant physical and performance characteristics:

*Material used:	Plastic and stainless steel(common to Models XP400 & XP1000)	
*Dimensions(LxWxH):	(Model XP400)	56.5x60.0x45.0cm
	(Model XP1000)	65.7x76.8x51.0cm
*Net Weight:	(Model XP400)	30.0Kg
	(Model XP1000)	58.0Kg
*Film sizes to be processed:	10~36cm side x 91.4cm long(common to XP400/XP1000)	
*Film type:	Ordinary films(sheet films)..common to XP400/XP1000	
*Chemistry type:	Ordinary one for auto-processors...common to XP400/XP1000	
*Tank capacity:	(Model XP400)	2.0L(DEV), 2.0L(FIX), 2.0L(WASH)
	(Model XP1000)	6.5L(DEV), 6.5L(FIX), 5.5L(WASH)
*Processing speed:	(Model XP400)	3/4/5 min. selectable(dry to dry)
	((Model XP1000)	90/110/150sec.(dry to dry)
*Film processing capacity:	(Model XP400)	Max. 61 x 14"x17" film at 3 min. speed
	(Model XP1000)	Max. 83 x 14"x17" film at 90sec. Speed
*Water consumption:	Within 3L/min.(common to XP400/XP1000)	
*Film drying method:	I.R. Heater(common to XP400/XP1000)	
*Automatic standby:	Yes(common to XP400/XP1000)	
*Light proof cover:	Yes(common to XP400/XP1000)	
*Power source:	Single phase,110~120V, 60Hz.(common to XP400/XP1000)	

(5) Intended use: To be used for processing of radiographed films.

(6) Technological characteristics: See the above (4).

(b) 510(k) summaries for those premarket submissions in which a determination of substantial equivalence is also based on an assessment of performance data

(1) A brief discussion of the nonclinical tests submitted: :
Both of Models XP400 & XP1000 "PASSED" JQA Tests against (1) Power Input, (2) Protective Earthing, (3) Excessive Temperatures, (4) Continuous Leakage Currents and (5) Dielectric Strength.

(2) The conclusions drawn from the nonclinical and clinical tests that demonstrate that the Device is as safe, as effective, and performs as well as or better than the legally marketed Device identified in paragraph (a),(3) of this section:

(c) This "510(k) Summary" is submitted in a separate section of the submission.

(d) Any other information reasonably deemed necessary by the agency: Not applicable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 3 2003

Daito Co., Ltd.
% Mr. Edward Epstein
Jade, Ltd.
945 Main Street, Suite 312
MANCHESTER CT 06040

Re: K024342
Trade/Device Name: Radiographic Film Processors
Models XP400 & EP1000
Regulation Number: 21 CFR 892.1900
Regulation Name: Automatic radiographic
Film processor
Regulatory Class: II
Product Code: 90 IXW
Dated: March 27, 2003
Received: March 31, 2003

Dear Mr. Epstein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K024342

Device Name: Daito XP400 & XP1000

Indications For Use:

Developing exposed x-ray film.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K024342

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)